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7.+Testimony: The Michigan Health Ministries of Ascension Health submit the following comments pursuant to the Public Hearing held on October 31st proposing modifications to Urinary Extracorporeal Shock Wave Lithotripsy, Psychiatric Beds and Services, and Cardiac Catheterization Services. We generally support the modifications being proposed to these CON Standards. We further appreciated the opportunity to participate in the various Standard Advisory Committees, and in some instances workgroup meetings that convened to deliberate on modifications proposed to each respective standard.

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7. +Testimony: Spectrum Health supports the proposed revisions to the CON Review Standards for Cardiac Catheterization, as presented to the CON Commission at their meeting on September 18, 2007. The Standards Advisory Committee (SAC) for Cardiac Cath Services has completed an excellent job of revising the CON Review Standards. The updated procedure weights and the requirements for advanced pediatric cardiac services represent significant improvements in bringing these Standards in line with the contemporary practice of cardiology. Furthermore, the Standards retain the requirement that elective angioplasty should be performed only in hospitals which have on-site open-heart surgery back-up. This recommendation conforms to the guidelines of the American College of Cardiology (ACC), which represents the best judgment of the profession. Spectrum Health supports the recommendations of the Cardiac Cath SAC, and urges final approval of these proposed Standards at the CON Commission meeting on December 11, 2007.

1. +Name: Wayne Cass
2. +Organization: EAM/International Union of Operating Engineers, Local 547
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6. +Misc: OHS
7. +Testimony: CON Commission Public Hearing on Proposed Actions Approved
at the September Commission Meeting
Testimony presented on behalf of the Economic Alliance for Michigan
By Wayne Cass, Business Manager
International Union of Operating Engineers, Local 547

These comments represent the consensus perspective of both the business and labor members of the Economic Alliance for Michigan (EAM) regarding the proposed actions approved at the September meeting of the Commission for the Cardiac Cath and Open Heart Surgical Standards.

Cardiac Cath Standards

EAM supports the proposed action to changes to the CON standards for Cardiac Catherization requiring facilities providing Cardiac Services in Michigan to participate in the American College of Cardiology National Cardiovascular Data Registry's CathPCI Registry. EAM also supports requiring facilities proposing to initiate a pediatric Cardiac Cath service to meet certain guidelines of the American Academy of Pediatrics. EAM supports maintaining the provision of the CON Standards that Elective Angioplasty should ONLY be done at hospitals with on-site Open Heart Surgery Programs.

Open Heart Surgical Centers

EAM supports the proposed action to change the CON standards for Open Heart Surgical (OHS) programs requiring facilities providing OHS in Michigan to participate in the Society of Thoracic Surgeons database and this program's state-wide auditing. We support the proposed action to maintain the minimum volume for new programs at 300 per year, to increase the minimum volume for attending physicians from 50 to 75/ year and requiring consulting hospitals to perform a minimum of 400 cases per year for at least three consecutive years.

EAM members believe that there are currently an adequate number of OHS Programs in Michigan that are well distributed across the state and patient access is NOT an issue. Therefore, we support the proposed action to limit the ability of hospitals to commit their OHS discharge data to only the data not previously committed and thereby eliminating the recycling of the same discharge data every 7-years in order to justify additional OHS programs. EAM supports the MDCH staff's (S-3) recommendation to refine the methodology for projecting the potential need for new OHS programs. EAM supports the recommended additions and deletions in the procedure codes that define OHS and the elimination of invalid procedure codes or procedure codes that had little or no predictability value. We further support the adjustment in the number of OHS procedures projected by this methodology to the actual number of OHS procedures performed. These MDCH staff recommended refinements in the methodology have gone a long way to simplify the process and improves its predictability.

In addition to my comments regarding proposed actions approved at the September Commission meeting, we would like to express our support to the comments made on behalf of EAM presented by Ms. Marsh Manning, from General Motors, regarding the 2008 CON Work Plan.

**CRITTENTON HOSPITAL
MEDICAL CENTER**

Caring Professionals Committed to Excellence

RECEIVED

OCT 31 2007

October 26, 2007

Certificate of Need Commission
Michigan Department of Community Health
Lewis Cass Building
320 South Walnut
Lansing, MI 48903
Attn: Norma Hagenow, Chairperson

Re: Public Comments, Open Heart Surgery Standards

Dear Ms. Hagenow:

Crittenton Hospital Medical Center (CHMC) recognizes the complexity of the issues surrounding Cardiac Surgical Programs Certificate of Need standards and applauds the work performed by the special advisory committee for open heart surgery and we agree with many of its analysis and recommendations. However, we are confused by the report given by the Open Heart SAC to the CON Committee at its September 17th meeting, and take issue with one specific recommendation. As part of its delegated function, the committee reviewed the volume standards for initiating and maintaining open heart surgical programs in the State of Michigan. The advisory committee in its report to the full committee fully acknowledged the complexity of the literature regarding volume as a surrogate for quality, and acknowledged the wide spread presence of low quality, high volume programs as well as high quality, low volume cardiac surgical programs. They went on to say that there is no a priori magic number for program certification and therefore they were strongly recommending that all programs be required to participate in a nationally recognized cardiac surgical data base as well as participating in the State's cardiac surgical consortium, a consortium dedicated to the improvement of cardiac surgical services in Michigan. Despite the above acknowledgements, they recommended no change in the current standards based primarily on volume criteria for program approval. Quite frankly the report does not seem to warrant this recommendation.

We at Crittenton believe that the State, the public and the purchasers of healthcare should not have to rely on surrogates of quality when in fact direct measurements of quality of cardiac surgical programs exist. Looking at the well recognized monitors of quality, i.e., structure, process, and outcomes, we believe that the State's CON standards for current cardiac surgical programs should focus on these easily definable metrics. If this model were to be adopted, volume measurements would become one of the many measurements

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of a program's quality and its ultimate viability. Metrics such as effective program governance, stability of cardiac surgical teams, stability of intensive care nursing staffing, the breadth and complexity of the surgeries performed, and institutional resources committed to the program and available for continued program support would become the new standards. Additionally and probably most importantly, would be metrics of patient satisfaction and confidence in the program, confidence due to the transparent sharing of surgical outcomes data with the public at large. Though we understand that such standards may be difficult to build a consensus around, and while we understand that should a consensus be accomplished such standards may be difficult for the State to measure compliance with, we cannot endorse a simple default to a surrogate volume position. We especially cannot support that recommendation when the default position identifies three different levels of volume and therefore three different quality levels for the program throughout the State. If volume criteria is a surrogate for quality, can we really continue to support a three tier system of quality for our cardiac surgical programs throughout the State? The answer is obviously no, and therefore it is time to reject the volume reference as a sole determinant for which programs are of high quality and which are of low quality.

If one were to however argue that volume requirements represent an assessment of a community needs position, then an entirely new set of arguments pertain. Crittenton Hospital Medical Center agrees that hospitals should be required to put forth and demonstrate a community need for a new cardiac surgical program (a requirement that was carefully followed and met by CHMC in filing its CON application using the methodology as required by the CON.) However, that need, once demonstrated for opening a program is not currently being reassessed in determining the ongoing functioning of a program. The community needs for a program are based, or at least should be based on a population's disease incidence and their relative access to receive care and intervention for that disease. Although rates of treatment do vary from time to time, especially with the advent of new technology such as has occurred in the field of cardiovascular disease, the population's need for such services remains well documented in the State's database. What has changed since the filing of our initial application is the opening of additional programs altering the supply/demand ratio in our particular case.

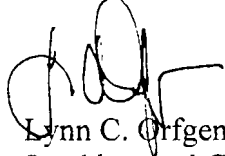
CHMC is proud of the cardiac surgical program we have built in partnership with the University of Michigan's cardiovascular services. With direct oversight by Dr. Richard Prager, Head, Division of Adult Cardiac Surgery at the University of Michigan, with surgical services provided by the University of Michigan faculty members living in the community, and with outcomes we know to be outstanding (including the performance of complicated valve repair and replacement surgery), we know we are fulfilling a community need with our cardiac surgical program and our interventional cardiac program.

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In closing, Crittenton Hospital Medical Center strongly supports these recommendations:

- a. that opening of a new cardiac surgical program should be based on a demonstrated real and valid assessment of a community's need for such a program and the population demographics to support it.
- b. that all programs have a demonstrated commitment to quality based on governance, structure and outcome measurements for maintenance of programs currently in existence, and that the State rejects arbitrary and inconsistent volume statistics as the sole criteria by which programs are maintained.
- c. that the State performs an ongoing assessment of a community's need for existing programs and the population's access to readily available acute cardiac care services in their community.

Sincerely,



Lynn C. Orfgen
President and CEO

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7. +Testimony: The Michigan Health ministries of Ascension Health appreciates the opportunity to comment on changes to CON Standards for Open Heart Surgery Services. We are concerned about language in the Proposed Amendment (S-3), page 8, beginning on line 378 that appears to give the Department authority to "modify" the methodology related to Open Heart Utilization weights without requiring Standard Advisory committee action, a public hearing, or submittal of the standard to the Legislature and Governor in order to become effective. If the intent of the Department is simply to re-run or update the weights periodically we would ask that the language be reworded such that it could not be interpreted in a way that allows for substantive modification of the methodology without an open and deliberative process.

Thank you for the opportunity to comment.

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7. +Testimony: Henry Ford Health System supports the work done by the Standard Advisory Committee and the follow-up work done by the informal workgroups and MDCH to finalize the weights that are used to compute open heart cases. Although the SAC did not have time to finalize their work, they made several changes that improve the standards and make them a more accurate reflection of today's practice of cardiac care. There was a code by code review of the diagnostic codes that are used to determine the number of open heart surgery cases that a facility's discharges will generate. These codes continued to be reviewed, tested and revised by the Department after the SAC was concluded and the resulting list now seems to be comprehensive and accurate. Furthermore, the Department has reviewed and revised the list of procedures codes that are considered open heart procedures and again the resulting list seems to be much more refined than was the previous. In addition, MDCH developed a revision to the methodology that uses predominately data from facilities that already have open heart surgery to project need. The end result of this process has been to tighten the diagnoses that predict cases, the procedures that count as cases and the data that is used to project need so that very few, if any, new programs would be possible under these standards.

In addition, the SAC made changes to the data commitment process, making it more restrictive than the current rules. The ability to reuse previously committed data after 7 years has been removed and now the facility committing data can only use incremental data in support of another institution. Furthermore, a facility that experiences growth may use its own data if there is sufficient to meet the volume requirements specified in the standards. These changes eliminate the recycling of the same data in support of additional programs, while still allowing facilities that experience growth due to market demographics the chance to provide a needed service. We would recommend that the Commission approve the changes in the standards as proposed.

Finally, the standards now contain a requirement that new programs participate in the STS quality improvement database. The SAC was provided with information showing how measurable improvements occurred as a result of best-practice sharing through this reporting and monitoring mechanism. Currently, all existing OHS programs in Michigan participate in this effort therefore it makes sense that any new programs should be required to do the same.

I appreciate the opportunity to be a member of the Standard Advisory Committee that reviewed the Open Heart Surgery Standards and thank you for the opportunity to provide these comments on the proposed standards. I would recommend that the Commission accept the standards as written.

Aaron Kugelmass MD
Director, Cardiac Catheterization Services
Henry Ford Hospital

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7. +Testimony: Spectrum Health endorses the conclusion that there is no need for additional open-heart surgery programs in Michigan and that the citizens of the state are well-served by the existing programs. We support the major recommendations of the Open-Heart Surgery Standards Advisory Committee (SAC), namely: 1) that all open-heart programs should participate in the STS database; 2) that the minimum volume for open-heart surgery should remain at 300 cases per year; and 3) that hospitals should not be able to repeatedly commit their inpatient data to new open-heart surgery CON applications every seven (7) years. To this last point, Spectrum Health supports the ability of a particular hospital to use their own data to justify a new program, even if they previously committed data to another CON application. However, we recognize the legal issues that have been raised about this provision and accede to the legal conclusion of the Attorney General.

The SAC asked the Department to complete the task of updating the methodology for projecting new open-heart surgery cases and address the inadequacies of the existing methodology. In the process of updating the need methodology, Department staff identified shortcomings of the existing methodology which appear to artificially inflate the projected need. Specifically, the previous process of calculating weights for the identified diagnosis categories artificially inflated the importance of secondary diagnoses. This is because the same sets of weights were applied to both primary and secondary diagnoses. In order to minimize the overemphasis on secondary diagnoses, the Department computed two (2) sets of weights – one for primary and one for secondary diagnoses. Referred to as “S-3,” this approach does a better job of balancing the impact of primary and secondary diagnoses and, hence, minimizes the over estimate of need for open heart programs. Spectrum Health endorses

the proposed S-3 need methodology and supports incorporating this change into the revised open-heart surgery standards.

Spectrum Health supports the proposed revisions to the CON Review Standards for Open-Heart Surgery, including the S-3 need methodology, and urges final approval of these proposed Standards at the Commission meeting on December 11, 2007.

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- 7. +Testimony: Forest View Hospital is a contract provider of inpatient and partial hospitalization services for network180 consumers. We value the service that Forest View provides our consumers and support its continuance.

We work with local providers, such as Forest View, to keep lengths of stay appropriate, to divert those appropriate to lesser intensity services, and allow our consumers to remain close to their homes while inpatient.

Nonetheless, Network180 frequently experiences shortages in bed availability at local hospitals, leading network180 to contract with eleven hospitals in the western half of Michigan in order to obtain sufficient inpatient capacity. Unfortunately, this results in Kent County consumers being placed as far as 100 miles from home for inpatient treatment.

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7. +Testimony: Holland Hospital is supportive of the proposed changes to the CON Review Standards for Psychiatric Beds and Services. The proposed reduction of the minimum size of a psychiatric unit makes sense, especially for psychiatric services provided in community hospitals, like Holland. Adjustments to the definitions of planning area and relocation zone permit existing and proposed providers of psychiatric services sufficient latitude to establish and locate needed services, without unduly impinging on the market areas of other providers.

The reduction of the minimum occupancy requirements to 60% for adult beds and 40 % for child and adolescent beds is reflective of the reality that is contemporary acute psychiatric care, in which occupancy fluctuates substantially, especially by season. Such wide fluctuations prohibit maintenance of a higher average occupancy. This is especially true for smaller psychiatric units, where a change in average census of one (1) patient can impact occupancy by 8-10%.

Similarly, the high occupancy provision for adding needed psychiatric beds provides a needed safety valve for highly utilized psychiatric programs. The differential requirements for larger and smaller psychiatric units also recognizes the difficulties of operating psychiatric units less than 20 beds and the mathematical limitations of small numbers.

As a representative of Holland Hospital, I participated in the Work Group process that led to the drafting of these proposed changes to the Standards. I would like to complement Commissioner Deremo and MDCH staff member Andrea Moore for their efforts in guiding the group to consensus through many difficult and potentially divisive issues. They are to be commended.

Holland Hospital appreciates the opportunity to comment on the CON Review Standards for Psychiatric Beds and Services, and we urge the CON Commission to approve them at their meeting on December 11, 2007.

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7. +Testimony: October 29, 2007

Certificate of Need Commission
Michigan Department of Community Health
Lewis Cass Building
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Dear CON Commissioners,

Henry Ford Health System supports the changes that are proposed to the standards for psychiatric beds and services. Specifically, the recommendation to revise the definition of the Planning Area from individual counties to the Health Service Area makes sense because in many cases, the patients served in today's psychiatric hospitals or units come from outside the county boundaries. For example, at Henry Ford Kingswood Hospital, which is located in Oakland County, more than 50% of the patients originate from Wayne and Macomb counties. Allowing for this more expansive definition of the planning area will better reflect patient origin, especially when coupled with the fact that service areas for psychiatric services are generally much larger than those defined for acute care services.

A second change that we support is the expansion of the replacement zone from 2 miles to 15 miles. This change will allow facilities that are located in densely populated and fully developed areas where no suitably sized replacement sites can be found the flexibility to explore the availability of other locations within the planning area.

Finally, we also support the addition of language that allows for the expansion of services if the hospital can justify it due to high occupancy. This provision is similar the adjustment that is provided for acute care services and allows facilities the flexibility to expand when their occupancy reaches benchmark levels over an extended period of time. There is also a requirement that the number of licensed beds will be reduced if the applicant does not meet occupancy targets after adding beds, thereby building in the need for a business case to justify the additional beds in the first place.

We would also like to comment on the process that was used to lead the workgroup through the review of these standards. The group, lead by Commissioner Deremo, was all-inclusive and transparent in its actions. Excellent meeting support was provided by MDCH staff. Meetings were announced well in advance and meeting materials were distributed with plenty of time to be reviewed. The group achieved consensus on most, if not all issues, and overall the group seemed intent on developing good public policy and putting the interest of patients to the forefront.

Henry Ford Health System appreciates the opportunity to comment on these standards and would urge the Commission to adopt them.

Yours truly,
Elizabeth C. Palazzolo
Director, Planning & Research
Henry Ford Health System

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7. +Testimony: Greater Michigan Lithotripsy (GML) is a partnership involving hospitals and physicians established to provide mobile lithotripsy services to the citizens of Michigan. We are involved in three (3) mobile lithotripsy routes in the state, serving more than a dozen host sites in lower Michigan.

In general, GML is supportive of the proposed changes to the Standards. We believe that the changes made regarding initiation and replacement of lithotripsy machines serve to tighten the standards in a constructive manner. However, we would like to reiterate our concerns about the excessively high standard remaining in the Standards for expansion of a mobile lithotripsy service. We have asked our management company, American Kidney Stone Management, Ltd. (AKSM), to review their national case loads to determine the typical volume for mobile lithotripters. AKSM is the country's second largest lithotripsy service provider and manages over 50 mobile and fixed-site lithotripters for some 20 independently-owned companies across the country.

Nationwide, on average, a mobile lithotripter performs 600 cases per year. The maximum number of cases performed on any single mobile lithotripter is 1,200 cases. Generally speaking, once case volume exceeds 1,000 cases per machine, a second mobile lithotripter is added. After a mobile route adds a second lithotripter, overall route volume increases. This is because a single mobile lithotripter treating 1,000 cases annually is subject to increased down time for maintenance and is unable to be physically transported in a timely fashion to satisfy the required demands of dispersed communities. If another machine is not added to a route doing 1,000 or more annual treatments, the result is that patients have their treatments postponed or are treated invasively.

In light of the nationwide experience of our partner, AKSM, we believe that the CON requirement for expansion of an existing mobile lithotripsy route, 1,800 procedures per unit annually, is excessive. We recommend that a volume requirement more consistent with national experience, as cited above, should be incorporated into the CON standards for expansion of a mobile lithotripsy route. Specifically, GML recommends that an existing mobile lithotripsy service should qualify for expansion when its existing mobile unit(s) average 1,200 procedures, and should be able to project an average of at least 800 procedures for each existing and proposed machine on the route.

GML appreciates the opportunity to comment on the CON Review Standards for UESWL, and we urge the CON Commission to consider our suggested improvements.